Application No.: 10/557,072

Office Action Dated: June 30, 2008

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently amended) Process for preparing modafinil having a defined

granulometry which comprises the steps of:

a) preparing a solution of DMSAM in a solvent;

b) contacting the solution obtained with NH₃ at a predetermined temperature and

under a predetermined stirring; and

c) isolating the modafinil formed,

wherein said temperature and said stirring are predetermined in order to obtain said defined

modafinil having a granulometry wherein the ratio of median to mean is from 1:3 to 1:0.3 and

of median to mode is from 1:3 to 1:0.3.

2. (Original) Process according to claim 1, wherein the solvent is a protic polar

solvent.

3. (Original) Process according to claim 2, wherein the solvent is an alcohol.

4. (Original) Process according to claim 3, wherein the solvent is methanol.

5. (Original) Process according to claim 4, wherein the solution of DMSAM has a

concentration of DMSAM of between 1 and 1.25 mol L⁻¹.

6. (Previously presented) Process according to claim 1, wherein the temperature

in step b) is held between 15 and 65°C.

7. (Currently amended) Process according to claim 1, wherein the predetermined

stirring speed in step b) is chosen such that the modafinil isolated in step c) has a

granulometric median of between 2 and 60 µm, preferably between 15 and 45 µm.

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8. (Previously presented) Process according to claim 1, wherein in step b), the

solution of DMSAM is contacted with 3 to 6 molar equivalent of NH₃.

9. (Original) Process according to claim 8, wherein, in step b), the solution of

DMSAM is contacted with 3.2 and 5 molar equivalent of NH₃.

10. (Previously presented) Process according to claim 1, wherein, in step b), the

NH₃ is introduced into the solution over a sufficient time to obtain a complete dissolution

of NH₃.

11. (Original) Process according to claim 10, wherein, in step b), the NH₃ is

introduced into the solution over a time of between 2 h and 6 h.

12. (Original) Process according to Claim 11, wherein, in step b), the NH₃ is

introduced into the solution over a time of between 3 h and 4.5 h.

13. (Previously presented) Process according to claim 1, wherein, in step b), the

solution is contacted after the introduction of the NH₃ for a contact time sufficient to allow

the polymorphic transformation of form III to form I.

14. (Original) Process according to claim 13, wherein the contact time is between

8 and 12 h.

15. (Previously presented) Process according to claim 1, wherein the solution

obtained after step b) is further maintained at a temperature lower than the predetermined

temperature of step b) for a time sufficient to obtain complete crystallization of modafinil.

16. (Original) Process according to claim 15, wherein the solution is further

maintained at a temperature lower than the temperature of step b) for a time of from 1 h to

4 h.

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17. (Previously presented) Process according to claim 15, wherein the

temperature is between -20°C and 0°C.

18. (Previously presented) Process according to claim 1, wherein the modafinil is

isolated in step c) by filtration.

19. (Previously presented) Process according to claim 1, wherein the solvent in

step a) comprises water.

20. (Original) Process according to claim 19, wherein the solvent contains from

5% to 20% by volume of water.

21. (Previously presented) Process according to claim 19, wherein the NH₃ is

introduced into the solution in step b) over a time of between 4 h and 5 h.

22. (Previously presented) Process according to claim 19, wherein, in step b), the

solution of DMSAM is contacted with 5 to 5.5 molar equivalent of NH₃.

23. (Previously presented) Process according to claim 1, which does not include a

recrystallization step after step c).

24. (Previously presented) Process according to claim 1, which does not include a

grinding step after step c).

25. (Previously presented) Process according to claim 1, wherein the

predetermined temperature and stirring speed are chosen such that particles of modafinil

form I of which at least:

- 50% have a diameter of less than 45 μ m, and

- 80% have a diameter of less than 110 μm, and

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- 95% have a diameter of less than 220 μm,

are isolated in step c).

26. (Previously presented) Process according to claim 1, wherein the modafinil

isolated in step c) is modafinil form III.

27. (Previously presented) Process according to claim 1, wherein the modafinil

isolated in step c) is modafinil form I.

28. (Previously presented) Process according to claim 1, wherein modafinil with a

granulometric median of between 1 µm and 1 mm is isolated in step c).

29. (Original) Process according to claim 1, wherein the levorotary enantiomer of

DMSAM is employed in step a).

30. (Original) Process according to claim 1, wherein the dextrorotary enantiomer

of DMSAM is employed in step a).

31. (Canceled)

32. (New) Process according to claim 7, wherein the predetermined stirring speed

in step b) is chosen such that the modafinil isolated in step c) has a granulometric median

of between 15 and 45 µm.

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